



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 3, 2014

Arthrex, Incorporated
Mr. Leon Brown II, Ph.D.
Regulatory Affairs Specialist
1370 Creekside Boulevard
Naples, FL 34108-1945

Re: K141635

Trade/Device Name: Arthrex iBalance® TKA System

Regulation Number: 21CFR 888.3565

Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated
uncemented prosthesis

Regulatory Class: Class II

Product Code: MBH, JWH

Dated: June 12, 2014

Received: June 19, 2014

Dear Mr. Brown:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Lori A. Wiggins -S

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K141635

Device Name

Arthrex iBalance® TKA System

Indications for Use (Describe)

The Arthrex iBalance® TKA System is indicated for use in individuals undergoing surgery for:

- Painful, disabling joint disease of the knee resulting from degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis;
- Post-traumatic loss of knee joint configuration and function;
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability;
- Revisions of previous unsuccessful knee replacement or other procedure.

Additional indications for posteriorly stabilization components:

- Ligamentous instability requiring implant bearing surfaces with increased constraint;
- Absent or non-functioning posterior cruciate ligament.

These devices are single use only and are intended for implantation with bone cement, with the exception of porous coated femoral components which can be used cemented or uncemented (biological fixation).

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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2.6 510(K) SUMMARY

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| Date Summary Prepared | August 28, 2014 |
| Manufacturer/Distributor/Sponsor | Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA |
| 510(k) Contact | Leon Brown II, Ph.D. Regulatory Affairs Specialist Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 72028 Fax: 239/598.5508 Email: Leon.Brown@Arthrex.com |
| Trade Name | Arthrex iBalance® TKA System |
| Common Name | Knee Prosthesis |
| Product Code -Classification | JWH, MBH |
| Name | 888.3565: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis. |
| CFR | 888.3560: Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer |
| Predicate Device | K081127: Accin™ Total Knee System K121771: Zimmer® Persona™ Personalized Knee System |
| Purpose of Submission | This traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex iBalance® BioSync™ Femoral Components line extension to the current Arthrex iBalance® TKA System . |
| Device Description | The Arthrex iBalance® TKA System consists of femoral components, tibial tray, tibial bearing components and patellar components. All components are available in a range of sizes to fit varying anatomical requirements. Femoral components and tibial bearing components are available in both posteriorly stabilized (PS) and cruciate retaining (CR) configurations. Femoral components are available in left and right versions and are designed to work with the Arthrex dome patella components. Femoral and tibial tray components are manufactured from Cobalt-Chromium Alloy conforming to ASTM F-75. Tibial bearing and patellar components are manufactured from UHMWPE conforming to ASTM F-648. |
| | The Arthrex iBalance® BioSync™ Femoral Components |

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| | <p>line offers the option of affixing the system's femoral components without cement through the use of a titanium scaffold porous coating (biological fixation).</p> |
| Intended Use | <p>The <i>Arthrex iBalance® TKA System</i> is indicated for use in individuals undergoing surgery for:</p> <ul style="list-style-type: none"> • Painful, disabling joint disease of the knee resulting from degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis; • Post-traumatic loss of knee joint configuration and function • Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability; • Revisions of previous unsuccessful knee replacement or other procedure. <p>Additional indications for posteriorly stabilized components:</p> <ul style="list-style-type: none"> • Ligamentous instability requiring implant bearing surfaces with increased constraint; • Absent or non-functioning posterior cruciate ligament. <p>These devices are single use only and are intended for implantation with bone cement, with the exception of porous coated femoral components which can be used cemented or uncemented (biological fixation).</p> |
| Substantial Equivalence Summary | <p>The <i>Arthrex iBalance® TKA System</i> is substantially equivalent to the predicate device in which the basic design features and intended uses are the same. Any differences between the <i>Arthrex iBalance® TKA System</i> and the predicate are considered minor and do not raise questions concerning safety and effectiveness.</p> <p>The predicate <i>Arthrex iBalance® TKA System</i> is a total knee arthroplasty system consisting of femoral components, tibial tray, tibial bearing components and patellar components. The proposed <i>Arthrex iBalance® TKA System</i> consists of the same four components plus a line extension to the currently available femoral components. This Arthrex iBalance® BioSync™ Femoral Components line extension is equivalent to the currently available Arthrex predicate femoral components in size range, material, use and performance with the exception</p> |

that the Arthrex iBalance® BioSync™ Femoral Components have a titanium scaffold porous coating on their non-articulating side.

There have been no changes to the articulating surfaces of the femoral components. Fatigue, biocompatibility, metallurgical, corrosion, microstructure, strength, bonding, abrasion and ingrowth testing information submitted demonstrates that the Arthrex iBalance® BioSync™ Femoral Components are consistent with FDA Guidance regarding porous coated orthopedic implants.

Based on the indication for use, technological characteristics, and testing data submitted, Arthrex, Inc. has determined that the *Arthrex iBalance® TKA System* is substantially equivalent to currently marketed predicate devices.
